K102324

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY - 4 2011

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ENDO-FUSE® Intra-Osseous Fusion System.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd. Arlington, TN 38002
Date:	March 30, 2011
Contact Person:	Sarah Holtgrewe Manager, Regulatory Affairs (901) 867-4476
Proprietary Name:	**ENDO-FUSE® Intra-Osseous Fusion System**
Common Name:	Fusion Rod and Fusion Beam
Classification Name and Reference:	21 CFR 888.3040 –Screw, Fixation, Bone--Class II
Device Product Code and Panel Code:	Orthopedics/87/ HWC
Predicate Device	ROI Fusion Rods and Plates (K051309)

DEVICE INFORMATION

A. DEVICE DESCRIPTION

The ENDO-FUSE® Intra-Osseous Fusion System consists of titanium alloy triangular-shaped rods and "barbell" shaped beams intended for surgical implantation within the bone to create fixation. The rods are available in various lengths and diameters and the beams in various widths and lengths. Both rods and beams are roughened with a coating of CP titanium plasma spray which is important for achieving fixation via an interference fit inside the bone.

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B. INTENDED USE

The ENDO-FUSE® Intra-Osseous Fusion System Rods are generally indicated for the reduction and fixation of fractures appropriate for the size of the devices. They are indicated for use in the internal fixation of fractures, boney fusion, and non-unions. They are also indicated for reconstructive procedures where reduction and fixation of bone fragments are required (e.g. osteotomies.)

The ENDO-FUSE® Intra-Osseous Fusion System Beams are indicated for lateral column lengthening and for fusions of any joint in the foot/ankle appropriate for the size of the device, including tarso-metatarsal, metatarsal-cuneiform, calcaneal-cuboid, talo-navicular, LisFranc, Four-Corner, subtalar, and ankle joint.

C. PERFORMANCE DATA

The following performance data was used to support the safety and efficacy of the ENDO-FUSE® Intra-Osseous Fusion System:

- Mechanical Property Testing of Plasma Spray Coating
  Static shear strength testing per ASTM F1044, shear fatigue strength testing per ASTM F1160, and static tensile testing per ASTM F1147 were performed on worst-case coated test coupons. All test specimens passed, per the pre-defined acceptance criteria.
- Fatigue Testing
  Four-point bending fatigue testing was conducted on worst-case subject devices and compared to FDA-cleared devices. Results indicated that the subject devices were able to withstand higher cyclic loads than the predicate, and the acceptance criterion was met.
- Cadaveric Rod Insertion Testing
  Rod insertion testing was performed to investigate whether or not any clinically relevant distraction of the distal bone/fracture fragment occurs during rod insertion. The implantation results after insertion were deemed acceptable per the pre-defined acceptance criteria.
- Cadaveric and Mechanical Beam Distraction Resistance Testing
  Beam distraction resistance testing was performed on subject and predicate devices to show that the subject device could effectively prevent distraction of opposing bones after implantation. The subject device experienced greater distraction resistance than the predicate, and the acceptance criterion was met.

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The safety and efficacy of the ENDO-FUSE® Intra-Osseous Fusion System is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k), including the following: a device description and surgical technique comparison to the predicate, physical and mechanical property analysis of the plasma spray coating, FEA and mechanical

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fatigue testing comparison to predicate, rod insertion testing, an appositional bone analysis compared to predicate, and cadaveric beam distraction resistance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Ms. Sarah Holtgrewe
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

MAY - 4 2011

Re: K102324
Trade Name: Endofuse™ Inta-Osseos Fusion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 25, 2011
Received: April 26, 2011

Dear Ms. Holtgrewe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102324

Device Name: ENDOFUSE™ Intra-Osseous Fusion System

Indications For Use:

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Prescription Use **xxx** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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